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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/238,405	05/05/94	CAPON	D CELL5.3

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EXAMINER

HAYES, R

ART UNIT	PAPER NUMBER
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1647

41

DATE MAILED:

10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/329,405
238

Applicant(s)

Capon et al

Examiner

Robert C. Hayes

Group Art Unit

1647



☒ Responsive to communication(s) filed on Jun 26, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 57, 59, 64, 65, 67, 69, and 71 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 57, 64, 65, 67, 69, and 71 is/are rejected.

☒ Claim(s) 59 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Transitional After Final Practice

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 6/26/00 has been entered, as has been the after final amendment filed 12/13/99.
2. The rejection of claims 64-65, 67, 69 & 71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,359,046, is withdrawn due to the submission of the terminal disclaimer of 12/13/99 (paper #37).
3. The rejections of claim 69 under 35 U.S.C. 112, first paragraph, as containing new subject matter and under 35 U.S.C. 112, second paragraph, as being indefinite, are withdrawn due to amendment of the claim.
4. The rejection of claims 57, 64, 67, 69 & 71 under 35 U.S.C. 102(b) as being anticipated by Gross et al., is withdrawn solely because of the recitation, "in the absence of a T-cell receptor", in which the transfected cytotoxic T-cell hybridoma cells appear to contain endogenous wildtype

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T-cell receptors. It should be noted that this rejection may be re-instated depending on how Applicants amend the claims to overcome the new matter rejection below.

5. Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Applicants' arguments filed 12/13/99 as paper # 34 have been fully considered in the Advisory Action of 6/30/00, but they were not deemed to be persuasive.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57, 64-65, 67 & 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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In contrast to Applicants' assertions on page 2 of paper #34, pages 30-33 & 36 of the specification contemplates only a chimeric protein comprising the ζ chain of the Fc receptor to transduce a signal when "in the absence of a T-cell receptor"; thereby, constituting new matter, especially as it relates to claim 71.

It is suggested incorporating claim 59 into independent claim 57, followed by cancellation of claim 71 should obviate this rejection.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 57, 64, 67, 69 & 71 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kuwana et al., for the reasons made of record.

As previously made of record, in contrast to Applicants' assertions, Kuwana et al. teach all structural limitations currently recited in the claims, in which cytoplasmic calcium concentrations are induced; thereby, meeting the functional limitation that "initiation of a signal" has occurred. In that no claim limitations are recited that structurally require the ζ chain as the intracellular domain, Applicants' arguments remain not persuasive, for the reasons extensively

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made of record. It is also noted that the transfected EL4 cells do not reasonably contain endogenous wildtype T-cell receptors; thereby, meeting this limitation of amended claim 57.

It is suggested incorporating claim 59 into independent claim 57, followed by cancellation of claim 71 should obviate this rejection.

10. Claims 57, 64, 67, 69 & 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Eshhar et al. (US Patent 5,906,936 - Suppl. IDS Ref #B).

Eshhar et al. teach a membrane bound chimeric Ab/T-cell receptor protein (i.e., a tyrosine kinase; as it relates to claim 71) constructed by removing the TcR V domain and replacing it with an antigen binding domain from a single chain antibody V domain (e.g., cols. 5-7, Fig. 4; as it relates to claim 57). Eshhar's chimeric protein comprises a signal/leader sequence and an extracellular C region that is naturally joined to the transmembrane domain, as well as a cytoplasmic domain (e.g., col. 6 & Figs. 8-9), which transduces a signal, as evidenced by IL-2 production (e.g., col. 10 & Fig. 1; as it relates to claim 57). Transfection of this chimeric protein construct into mammalian Jurkat cells (e.g., cols. 8-9 & Fig. 4), which do not express the T-cell receptor (i.e., as evidenced by pg. 31 of the specification; as it relates to claims 57 & 64), and into cytotoxic T lymphocytes is then described (e.g., bottom of col. 3; as it relates to claims 67 & 69), in which neither of these cell lines would be recognized as foreign in an appropriate host due to their inherent "non-MHC restricted manner" (e.g., see cols. 11-12). Lastly, in that the T-cell

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receptor constant regions from the α , β , γ & δ chains are used in Eshhar's chimeric constructs (e.g., col. 4), the limitations of claim 71 are further met.

It is suggested incorporating claim 59 into independent claim 57, followed by cancellation of claim 71 should obviate this rejection.

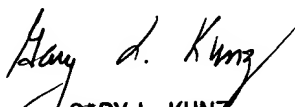
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
September 20, 2000



GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600